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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,670	08/27/2001	Jens Petersen	60117.000007	2509

7590 01/22/2009

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,670	PETERSEN ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,7-12 and 44-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 7-12, and 44-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed October 30, 2008 have been fully considered but they are not persuasive.

The applicant has argued that Annis (EP 0 248 544 A1) does not make obvious a viscosity of that claimed (2-60 Pa). The examiner disagrees. Both Annis and the applicant both are using a composition for the same use, soft tissue replacement. Even applicant discloses a very wide range of viscosities and further discloses that their composition may be either injectable OR have a shape/form to be implanted instead (pg.12, lines 6-12, 28-35; pg.15, lines 23-34-thus similar to viscosity and elasticity to Annis's implant). Also, the claim does not exclude the composition from having a defined shape or form.

The applicant further argues that Annis's implant is so rigid (too viscous) that it is capable of retaining sutures therethrough. The examiner disagrees. Annis clearly discloses that the implant cannot hold sutures (thus not rigid enough, too soft/flexible), this is the purpose of embedding a reinforcing sheet to which the sutures are anchored on the reinforcing sheet, not the hydrogel; it is further noted that reinforcing sleeve need not be used, an adhesive may be used instead. Annis discloses lower water contents provide for more rigid or stiff materials, thus the reason for the high (95%) water content, to provide *less rigidity and more flexibility* (col.2, lines 45-52), thus a viscosity similar to the applicants.

The applicant repetitively argued that Annis's endoprosthesis is used for a different prosthetic role. The examiner disagrees. Both Annis and the applicant's prostheses are used for as a soft tissue implant, for placement inside the body. Further, applicant has only claimed, "for

use as an endoprosthesis". First, the type of endoprosthesis or application is not specifically claimed or any structure that distinguishes over the prior art reference. Second, this is intended use language and all that is required is that the hydrogel be capable of implantation in the body, which it is. Additionally, as the composition of Annis is implanted, it is considered an endoprosthesis.

In summary, Annis is believed by the examiner to disclose a hydrogel having *all material components* claimed (water, acrylamide, methylene bis-acrylamide), the water having a high content the same as the applicants device (95 percent), therefore leaving the other components to have similar amounts and thus properties as claimed. Since exact amounts (of acrylamide and MBA) are not disclosed, it would have been obvious to modify the amount of components present in order to optimize the material properties of the composition for the desired application. As all implants in the medical field are in the same field of art. Also, the viscosity of applicant's composition must be one that at least allows the composition to remain with some form/shape, since it is disclosed to be non-degradable, non-soluble and in order for it to serve its purpose applicant would not want the composition to lose its form and migrate or travel through the body away from its intended purpose.

The applicant has argued that Purkait (EP0 895 785 A2) does not disclose a hydrogel that is an endoprosthesis itself. The examiner disagrees. The hydrogel (although within a shell) is an endoprosthesis, as the hydrogel is placed within a human body. The claim does not exclude the use of an outer shell. Further, it is noted that the applicant uses a shell/envelope, see claim 46, so it is unclear how the two are different. All that is required by the claim is a hydrogel for use as

an endoprosthesis, therefore, capable of being placed in the body. Purkait's hydrogel has this capability and meets the claim.

The applicant has also argued that Purkait's polymer is not bio-stable or non-degradable, non-soluble. The examiner disagrees. In example A, the cross-linked polymer (first component) is stable, non-degradable and non-soluble, see P0058. Although the linear polymer may migrate or be soluble, the cross-linked polymer is not.

The applicant has argued that Purkait's hydrogel contains three components, thus does not consist essentially of cross-linked acrylamide and water. The examiner disagrees. Referring to claim 1, the hydrogel is considered to be the cross-linked acrylamide composition ONLY-as this composition has capability of for implantation in the body separately, as it is a separate component before mixed with the other acrylamide. Referring to claims 51 and 51, the hydrogel is considered the entire three component composition and the polyacrylamide is considered only the cross-linked first component. The hydrogel in these claims does not consist essentially of; it is the acrylamide (first component) that consists essentially of. The first component of Purkait has the same materials claimed, in the same weight percentages claimed, with the viscosity claimed. The ratio is not disclosed nor the ppm or modulus. The composition of the first component of Purkait is VERY close to the applicants claimed hydrogel. It would have been obvious to have the ppm and ratio claimed, as this would require only routine experimentation to optimize the properties (viscosity and modulus-viscosity which is already the same as claimed) for the desired application.

The declaration under 37 CFR 1.132 filed October 30, 2008 is insufficient to overcome the rejection of claims 1, 2, 5-12, and 44-53 based upon Annis (EP 0 248 544 A1) and Purkait (EP 0 895 785 A2) as set forth in the last Office action because: Exhibit A contains no evidence, but instead opinions. Exhibit B contains some evidence showing various viscosities of different compositions such as honey, blood, creamer, etc., however no viscosities were listed for different compositions of poly acrylamide co methylenebisacrylamide. The remarks and evidence provided in the declaration is not sufficient in overcoming the rejection for the reasons in the response to arguments above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5, 7-12, 44-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1, 51, and 52 each require the polymer to be not water soluble and further resistant to degradation. It is unclear how the polymer (prior to be cross linked with methylenebisacrylamide) is insoluble, and resistant to degradation. It would seem that the hydrogel instead would be what is insoluble and resistant to degradation, not the acrylamide polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 7-12, 45, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annis et al; National Research Development Corporation, (EP 0 248 544 A1, cited in IDS). Annis discloses a biostable hydrogel (col.2, lines 32-38; it is clearly insoluble and non degradable) for use as an endoprosthesis (body 12 is implanted in the body, see fig.4) consisting essentially of a polymer of acrylamide cross-linked with methylene bis-acrylamide (col.3, lines 29-38) and water. Annis's hydrogel has a water content of 95 weight percent (col.2, lines 51-53; the same amount of water disclosed by applicant). Annis discloses a composition having the same material/monomer components claimed by the applicant. Although we know that the acrylamide and methylene bis-acrylamide of Annis is less than 4 percent by weight (since the water content is 95 percent and ammonium persulphate-also disclosed to be used by applicant-is 1 percent, leaving only 4 percent leftover), Annis is silent to mention the exact percent of acrylamide and methylene bis-acrylamide (MBA) and their ratio to one another. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio and amount of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component) of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the elastic modulus and viscosity, since such as inherent properties of the

material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Claims 1, 2, 5, 7-12, 44-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait, Mentor Corporation (EP 0 895 785 A2, cited in IDS). Referring to the claim 1 grouping, Purkait discloses a biostable hydrogel (first component; In example A, the cross-linked polymer-first component-is stable, non-degradable and non-soluble, see P0058. Although the linear polymer may migrate or be soluble, the cross-linked polymer is not) for use as an endoprosthesis (has capability alone, as it is once a separate component, further is placed in the body thus is considered an endoprosthesis) consisting essentially of polyacrylamide that includes acrylamide cross-linked with methylene bis-acrylamide (pg.7 line 55-56-pg.10, lines 32-34; example A, 1st component). Purkait's hydrogel has an acrylamide percent of 1-9 by weight (pg.7 lines 55-57; solid content of 2 percent, pg.10, lines 31-34) and the viscosity claimed (pg.10, lines 32-34, 15000-75000cps falls within claimed range). Purkait discloses a composition having the same monomers claimed by the applicant in the same weight percent and same viscosity, however Purkait is silent to mention the exact ratio of acrylamide to methylene bis-acrylamide (MBA). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component and acrylamide having the claimed weight percentages and viscosity) of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the

elastic modulus, since such are inherent properties of the material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Referring to claim 51 and 52 grouping, Purkait discloses a hydrogel (entire filling material in claim 1 and P0055) comprising a polyacrylamide (first component only; In example A, the cross-linked polymer-first component-is stable, non-degradable and non-soluble, see P0058. Although the linear polymer may migrate or be soluble, the cross-linked polymer is not) consisting essentially of acrylamide crosslinked with MBA (pg.6, line 58), wherein the hydrogel (entire filling material) comprises about 0.5 to 3.5 percent acrylamide by weight (disclosed to be 1-9 percents, so 1-3.5 falls within claimed range; pg.7, lines 55-56). Purkait discloses the hydrogel composition substantially as claimed (having the same water content and acrylamide content as applicant discloses; and claimed viscosity, pg.10, lines 32-34) however is silent to mention the exact ratio of acrylamide to methylene bis-acrylamide (MBA). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component and acrylamide having the claimed weight percentages and claimed viscosity) of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the elastic modulus, since such are inherent properties of the material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait, Mentor Corporation (EP 0 895 785 A2, cited in IDS) in view of Vogel et al. (US 6,660,301 B1). Purkait

discloses a polyacrylamide hydrogel for use as an endoprosthesis substantially as claimed (see above). Purkait does not however, disclose the use of cells on the endoprosthesis. Vogel teaches in the same field of polyacrylamide hydrogels, the use of a layer of cells on the endoprosthesis for the purpose of increased biocompatibility and attachment (col.6, lines 1-20; col.10, lines 30-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Vogel's teaching of using cells on polyacrylamide endoprostheses, with the polyacrylamide endoprosthesis of Purkait, in order to provide an endoprosthesis with increased biocompatibility and surface attachment.

Claims 1, 2, 5, 7-12, 44-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purkait (US 5,658,329). Purkait discloses a hydrogel (col.3, lines 50-55) comprising a polyacrylamide (col.3, lines 50-55; col.7, lines 49-53; col.7 line 60-col.8 line 67) consisting essentially of acrylamide crosslinked with MBA (col.7, lines 50-52, 60-65), wherein the hydrogel (entire filling material) comprises about 0.5 to 3.5 percent acrylamide by weight (disclosed to be 2-20 %, thus within claimed range; col.3, lines 52-53). Purkait's composition is inherently insoluble and non-degradable when in a cross-linked form-which Purkait discloses the polymer may be cross-linked or non-cross-linked (col.7, lines 50-52). Purkait discloses the hydrogel composition substantially as claimed (having the same water content and acrylamide content as applicant discloses; and claimed viscosity, col.3, lines 51-55) however is silent to mention the exact ratio of acrylamide to methylene bis-acrylamide (MBA). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio of acrylamide and MBA claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and water; water being the major component

and acrylamide having the claimed weight percentages and claimed viscosity) of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (amount and ratio of one to another-which would inherently provide the elastic modulus, since such are inherent properties of the material) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Claims 1, 2, 5, 7-12, 44, 45, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breza (US 3,661,659). Breza discloses a hydrogel (col.1, lines 71-75) comprising a polyacrylamide consisting essentially of acrylamide crosslinked with MBA (col.7, lines 10-22), wherein the hydrogel comprises about 0.5 to 3.5 percent acrylamide by weight (0.1-10 percent, within claimed range; col.7, lines 10-12). Breza's ratio of acrylamide to MBA seems to falls within the claimed range (col.7, lines 10-22). Breza's composition is insoluble and non-degradable (col.4, lines 46-49). Breza discloses the hydrogel composition substantially as claimed (having the same aqueous content and acrylamide content as applicant discloses) however is silent to mention the exact viscosity and other material properties of the composition claimed. Breza does disclose the viscosity may be widely varied for the particular application (col.6, lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material properties claimed, since wherein the general conditions (same material components acrylamide, methylene bis acrylamide, and aqueous fluid; aqueous being the major component and acrylamide having the claimed weight percentages) of a claim are disclosed in the prior art, it is not inventive to discover the optimum

or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738